

10/507281

DTec'd PCT/PTO 10 SEP 2004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. :

U.S. National Serial No. :

Filed :

PCT International Application No. : PCT/FR03/00797

VERIFICATION OF A TRANSLATION

I, Susan ANTHONY BA, ACIS,

Director of RWS Group Ltd, of Europa House, Marsham Way, Gerrards Cross, Buckinghamshire, England declare:

That the translator responsible for the attached translation is knowledgeable in the French language in which the below identified international application was filed, and that, to the best of RWS Group Ltd knowledge and belief, the English translation of the International Preliminary Examination Report of the international application No. PCT/FR03/00797 is a true and complete translation of the International Preliminary Examination Report of the above identified international application as filed.

I hereby declare that all the statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the patent application issued thereon.

Date: September 7, 2004



Signature :

For and on behalf of RWS Group Ltd

Post Office Address :

Europa House, Marsham Way,  
Gerrards Cross, Buckinghamshire,  
England.

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## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or Agent's file reference	FOR FURTHER ACTION		See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/FR 03/00797	International filing date (day/month/year) 12.03.2003	Priority date (day/month/year) 12.03.2002	
International Patent Classification (IPC) or national classification and IPC A61K9/06, A61K9/06			
Applicant ETHYPHARM et al.			

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets including this title page.

This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Instruction 607 of Administrative Instructions of the PCT).

These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:

- I  Basis of the report
- II  Priority
- III  Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV  Lack of unity of invention
- V  Reasoned statement according to Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI  Certain documents cited
- VII  Certain defects in the international application
- VIII  Certain observations on the international application

Date of submission of the demand 10.10.2003	Date of completion of this report 08.06.2004
Name and mailing address of the IPEA/  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0, Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer:  Rauter, A Telephone No. +49 89 2399-8645

**I. Basis of the report**

1. This report has been drawn up on the basis of the following elements (*the replacement sheets received by the receiving office in response to an invitation according to Article 14 are considered in the present report as "originally filed" and are not annexed to the report as they contain no amendments (Rules 70.16 and 70.17.)*):

**Description, pages:**

1-25 as originally filed

**Claims, No.:**

1-15, 16 (part) as originally filed

16 (part), 17-25 as amended (with, if appropriate, a declaration) according to article 19

**Drawings, sheets:**

1/9-9/9 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

- the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- the language of publication of the international application (under Rule 48.3(b)).
- the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- contained in the international application in written form.
- filed together with the international application in computer readable form.
- furnished subsequently to this Authority in written form.
- furnished subsequently to this Authority in computer readable form.
- The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

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4. The amendments have resulted in the cancellation of:

- the description, pages:
- the claims, Nos.:
- the drawings, sheets:

5.  This report has been written disregarding (some of) the amendments, which were considered as going beyond the description of the invention, as filed, as is indicated below (Rule 70.2(c)):

*(All replacement sheets comprising amendments of this nature should be indicated in point 1 and attached to this report).*

6. Additional observations, if necessary:

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty	Yes:	Claims	5,10,12,14,17-19
	No:	Claims	1-4,6-9,11,13,15,16,20-25
Inventive Step	Yes:	Claims	
	No:	Claims	1-25

Possibility of Industrial Applicability Yes: Claims 1-25  
No: Claims

2. Citations and explanations

**see separate sheet**

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**POINT V.**

1. The present notification mentions the following documents cited in the search report:

D1: WO-A-9 956 725

D2: WO-A-9 913 913

D3: EP-A-1 063 007

D4: Journal of Pharmaceutical Sciences, Vol. 88, No. 6, June 1999, pages 608-614

D5: FR-A-2 281 162

D6: Chem. Commun., 2001, 1556-1557

D7: Chem. Commun., 2001, 185-186

2. The present application does not satisfy the conditions set forth in Article 33(2) PCT, since the subject matter of the independent claims 1, 20, 21, 23 and 24 is not novel (see Rule 64(1)-(3) PCT).

D1 (see for example claims 1; 2, 3, 7; page 4, line 1 - page 5, line 10; page 6, lines 21-27) already refers to a composition comprising a hydrophobic organic liquid, an organogelling substance as defined and a bioactive substance; the composition changes into the form of an organogel when it comes into contact with an aqueous liquid. For the lack of novelty of the use and of the preparation processes as claimed see claims 11 and 14; page 6, lines 28-38; and also the examples.

The objection on the grounds of lack of novelty may also be based on the following documents:

D2: see, for example, page 6, line 12 - page 4, line 18;

D3: see, for example, Example 1.

The dependent claims 2-19, 22 and 25 contain no characteristic which, in combination with those of any of the claims to which they refer, defines a subject

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matter that satisfies the requirements of the PCT as regards novelty and/or inventive step, this being so because the organic liquids, organogelling substances and bioactive substances specified are mentioned in D1 (see, for example, page 4, line 15 - page 5, line 32; claims 1-3, 7; 12; examples). Documents D4-D7 are very relevant in particular for the judgment of an inventive step for the dependent claims.